

**RESPONSE TO OFFICE ACTION****A. State of the Claims**

Claims 1, 3, 5-8, 10, 13, and 17 have been amended. Claims 1-20 are pending. Support for amendment of claim 1 is found, for instance, at page 5, lines 3-4; support for the amendments to claims 3, 10 and 17 is found, for instance, in claim 1; support for the amendment of claims 5-8 is found at page 26, line 34 and following; support for the amendment of claim 13 is found in original claim 13. No new matter has been added. Thus, claims 1-20 are presented for reconsideration.

**B. Claims rejection under 35 U.S.C. § 112.**

The action asserts that claim 1(a) is vague and indefinite in that the metes and bounds of the phrase "...providing a first pool of polynucleotides...in accordance with the degeneracy of the genetic code..." are unclear regarding: (1) whether the tandem repeats of nucleic acid comprising degenerate nucleotide sequences necessarily encode the entire recombinant protein; and (2) "to what reference sequence the tandem repeat sequences comprise degenerate codons in accordance with the genetic code." Applicants respectfully request clarification, and traverse as they understand the rejection.

Regarding item (1), claim 1(a) recites "providing a first pool of nucleotides..."; however applicants note that this is prior to the subsequently recited annealing and extension steps. The provided pool of polynucleotides of step (a) will, at that point, necessarily encode only a portion of the sequence coding for a recombinant protein, containing repeating units, that is obtained following completion of the recited steps. Thus the objection appears unclear, in that it confuses the polynucleotide provided in step (a) with the polynucleotide obtained following, for instance, step

(f), and may also confuse the complete recombinant protein with the repeated (sub) units of the protein. Clarification is respectfully requested.

Applicants also respectfully note that the claim is fully definite as written in view of the specification. The specification describes embodiments in which a polynucleotide pool of claim 1 encodes repeats that comprise an entire recombinant protein eventually obtained (e.g. Example 1 as noted by the Examiner); or in which tandem (degenerate) repeats of nucleic acid encode a portion of a recombinant protein eventually to be obtained (e.g. Example 7 at pages 34-36). For instance, Example 7 describes embodiments of the invention in which peptides LKPNM and VPP are encoded separated by an FGPR protease cleavage site (page 35, line 10 and following). Additionally, the specification describes embodiments wherein the recombinant protein may, in addition to any repeating units, also comprise an affinity purification moiety (e.g. page 17, lines 7-14), or a transit peptide (e.g. page 24, line 21, to page 25, line 10).

Thus, claim 1 clearly claims, and the specification clearly describes, embodiments wherein the polynucleotide pool of claim 1 (a) encodes for a portion of a recombinant protein of claim 1. Claim 1 may therefore be clearly understood to cover either or both of these instances noted by the Examiner, and this in no way renders the claim indefinite.

Regarding item (2), as applicants understand it, there is no difference between the alternatives set forth by the action. That is, if the sequences are degenerate with regard to an alternative allelic sequence, they will also be degenerate with respect to one another. Additionally, at page 4, lines 4-22, page 11, line 20, and page 13, lines 3-15, for instance, the specification describes degeneracy with respect to the repeating peptide units of the recombinant protein. Applicants have also amended claim 1 to clarify this aspect. The amendment does not narrow the claim and thus Applicants do not intend to disclaim any subject matter by the amendment. It is

therefore believed that the rejection is now moot and removal of the rejection is thus respectfully requested.

The action asserts that claims 3, 10, and 17 are vague and indefinite in that the term "said tandem repeats" lacks antecedent basis. In response, Applicants note that claims 3, 10, and 17 have been amended to more clearly claim the invention. The amendments do not narrow the claims and thus Applicants do not intend to disclaim any subject matter by the amendments. It is believed that the rejection is now moot and removal of the rejection is thus respectfully requested.

The action asserts that claims 5-8 are vague and indefinite in that the metes and bounds of the phrase "encode polypeptides comprising at least 25%....of a desired amino acid" are unclear. In response, it is noted that Applicants have amended claims 5-8 to more clearly define their invention. The amendments do not narrow the claims and thus Applicants do not intend to disclaim any subject matter by the amendments. It is believed that the rejection is now moot and removal of the rejection is thus respectfully requested.

The action asserts that claim 13 is vague and indefinite in that there is no clear antecedent basis for the term "said vector" in claim 10, upon which claim 13 is dependent. Applicants respectfully note that claim 13 inadvertently included a typographical error in the previous response that indicated that the claim depended from claim 10 when in fact the original claim depended from claim 1. Applicants have listed claim 13 as amended herein to clarify that the claim depends from claim 1 as originally presented. The amendment does not narrow the original claim and thus Applicants do not intend to disclaim any subject matter by the amendment. It is believed that the rejection is now moot and removal of the rejection is respectfully requested.

The action asserts that claim 17 is vague and indefinite in that there is no clear antecedent basis for the phrase "wherein said expression vector further comprises...said recombinant protein

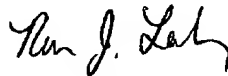
between said tandem repeats". In response, it is noted that Applicants have amended the claim. The amendment does not narrow the claims and thus Applicants do not intend to disclaim any subject matter by the amendment. It is believed that the rejection is now moot in view of the amendments to claims 13 and 17 and removal of the rejection is thus respectfully requested.

### C. Conclusion

In view of the above, it is submitted that all of the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned at (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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